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10/682,178

10/09/2003

Charles J. Link JR.

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DES MOINES, IA 50309-2721

EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/682,178	Applicant(s) LINK ET AL.	
	Examiner Anne L. Holleran	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 5-33, 75-84 and 86-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 34-74, 85 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

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DETAILED ACTION

3. The amendment filed 3/29/2007 is acknowledged. Claim 99 was added.

Claims 1-99 are pending. Claims 5-33, 75-84 and 86-98, drawn to non-elected inventions, are withdrawn from consideration. (Please note that the listing of non-elected claims has been corrected from the previous Office action, in which the non-elected claims were listed as 6-33, 75-84 and 86-98)

Claims 1-4, 34-74 and 85^{and 99} are examined on the merits. Claim 67 was examined to the extent that it reads on A549 cells and A375 cells (because A375 cells were found during routine search).

Claim Objections/Rejections Withdrawn:

Claim Objections

4. The objection to claims 47 and 85 are withdrawn in view of the amendments to the claims.

5. The rejection of claims 2 and 85 under 35 U.S.C. 102(b) as being anticipated by LaTemple (LaTemple, D.C. et al., Cancer Research, 59: 3417-3423, 1999; cited in IDS) is withdrawn in view of the amendments to the claims, where the claims now recite that the cells are human.

Claim Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34-65 and 68-74 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments and the declaration provided by Gabriela R. Rossi, filed under 37 CFR 1.132, have been carefully considered, but fail to persuade.

As the claims are currently set forth, they appear to be drawn to specific named species of cell lines, whereas the arguments provided by applicants appear to be directed toward genus claims. By reciting a specific name, the each of the claims is drawn to one specific cell line. This rejection would be obviated by making a deposit as outlined in the previous Office action, or by amending the claims with product-by-process language so that the claims were generic and did not recite a specific, named cell.

The previous rejection is reiterated below:

Claims 34-65 and 68-74 are drawn to compositions comprising specific cell lines that do not appear to be commercially available. The specification fails to provide enough information for one of skill in the art to produce cell lines with exactly the same characteristics as the cell lines of claims 34-65 and 68-74. Even if the specification did provide enough information for

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one of skill in the art to produce cell lines similar to those of claims 34-65 and 68-74, reproduction of identical cell lines is an unpredictable event. Because it does not appear that the cell lines of claims 34-65 and 68-74 are publicly available or can be reproducibly isolated from nature without undue experimentation, one of ordinary skill in the art cannot be assured of the ability to practice the claimed inventions. Because claims 34-65 and 68-74 require the cell lines of claims 34-65 and 68-74, a suitable deposit of the cell lines of claims 34-65 and 68-74 is required, or evidence must be provided that these cell lines are well known and readily available to the public, or that it is reproducible without undue experimentation.

Furthermore, unless a deposit was made at or before the time of filing, a declaration filed under the 37 C.F.R. 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited cell lines by its depository accession number, establish that the deposited cell lines are the same as that described in the specification, and establish that the deposited cell lines were in applicant's possession at the time of filing. Applicant is required to amend the specification to recite the accession number of the deposit, the date of deposit, a description of the deposited biological material, and the name and address of the depository. See *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

If the deposit is made under the provision of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be

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irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the Budapest Treaty as the treaty leaves this specific matter to the discretion of each member state.

If the deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit, over his or her signature and registration number, averring:

(a) that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

(b) that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

(c) that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

(d) that the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

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7. Claims 1, 3, 4, 66, 85 and 99 remain/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising attenuated tumor cells, where the cells comprise an $\alpha(1,3)$ galactosyltransferase encoding sequence, and where the cells express an α gal epitope on the cell surface, where the intended use of the claimed compositions is that of inducing an immune response to the α gal epitope, does not reasonably provide enablement for compositions having an intended use as vaccines, or comprising “vaccine tumor cells”. Applicants’ arguments have been carefully considered, but fail to persuade. Because claim 1 and claim 85 are drawn to compositions with the intended use of “inhibiting tumor growth” or broadly to “therapeutic compositions”, the claims encompass use for the prevention of cancer. Applicants’ arguments with respect to the definition of “vaccine” are noted, but the claims still read on the prevention of cancer claims with the intended use of preventing cancer, which is an intended use that is not enabled by the specification as explained in the previous Office action. Therefore, the rejection of record is maintained.

The previous rejection is reiterated below and is now applied to new claim 99:

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The basis for this rejection is that the specification fails to enable one of skill in the art to use the claimed compositions as prophylactic cancer vaccines for the intended use of preventing cancer.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation

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necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Because the claims contain the word “vaccine”, the implied intended use for the claimed compositions is that of a prophylactic cancer vaccine, in addition to other intended uses, such as that of “stimulating an immune response”. The specification provides no working embodiments demonstrating prevention of cancer using the claimed compositions. Therefore, the teachings of the specification are prophetic with respect to any use as a prophylactic vaccine.

For methods that relate to the prevention of cancer, there is no guidance in the specification for determining the appropriate time prior to the development of tumors to begin the therapy or for identifying patients at risk for developing those tumors. Further, Chamberlain (Chamberlain, R.S. et al. *Expert Opinion on Pharmacotherapy*, 1(4): 603-614, 2000) teaches that while vaccines are classically administered prophylactically to evoke an immune response capable of providing protection against infection by the same or similar pathogens for the treatment of infectious diseases, this has not been the approach in the field of cancer immunotherapy. In the treatment of infectious diseases, there is an a priori inoculation with a pathogen resulting in protection on subsequent encounter. However, cancer is not an infectious process. Cancer cells express a limitless number of antigens and a priori knowledge of who in the population is at risk for which cancer is lacking (see page 604, 1st column, first full paragraph). The specification provides insufficient guidance in regard to the issues raised above and provides no working examples which would provide guidance to one skilled in the art and no

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evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to use the claimed compositions as preventative vaccines.

Thus, in view of the contemporary knowledge in the art of the general lack of successful applications of vaccines for the prevention of human cancer as discussed above, as well as the lack of sufficient guidance in the specification, one of skill in the art would be forced into undue experimentation in order to use the inventions as claimed as vaccines.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 85 remains rejected under 35 U.S.C. 102(b) as being anticipated by Link, Jr. (Link, Jr. et al., US 5,869,035; issued Feb. 9, 1999).

Claim 85 is drawn to killed tumor cells that have been transformed with $\alpha(1,3)$ galactosyltransferase cDNA.

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Link, Jr. (US 5,895,035) teaches A375 cells that have been transformed with $\alpha(1,3)$ galactosyltransferase cDNA and then killed by treatment with human complement (see column 15, lines 1-29). Thus, Link, Jr (US 5,895,035) teaches compositions that are the same as that claimed.

Applicants's arguments have been carefully considered, but fail to persuade. Applicants assert that the amendment to claim 85 obviates the rejection of record, because the cells in claim 85 are killed by irradiation, which is not the cell killing method taught by Link, Jr. However, claim 85 is a product-by-process claim, and it is the product, not the process that is compared with the prior art. The process recited in claim 85 produces cells that have been transformed with $\alpha(1,3)$ galactosyltransferase cDNA and that are killed, which are the same as the cells that are taught by Link, Jr. The fact that Link, Jr.'s method of killing is different is not considered in comparison with the prior art because the method of killing does not appear to change the physical structure of the claimed cells. Therefore, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 67 and 85 are rejected under 35 U.S.C. 103(a) as being obvious over Galili (Galili, U. et al., Journal of Hematotherapy & Stem Cell Research 10: 501-511, 2001; cited in IDS) in view of Link, Jr. (Link, Jr. et al., US 7,005,126 B1, issued Feb. 28, 2006; effective filing date June 8, 1999) or Yoshimura (Yoshimura, N. et al., Cancer Letters, 164: 155-160, 2001, March; cited in the IDS).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-3, 67 and 85 are drawn to compositions comprising mixtures of a carrier and attenuated human tumor cells that comprise an $\alpha(1,3)$ galactosyltransferase encoding sequence, and which express α -gal on the surface of the cell. In claim 67, the human tumor cells are selected from a group of specific cell lines and may be A375 cells. In claim 3, the tumor cells are selected from the group of various carcinomas or adenocarcinomas.

Galili teaches compositions of leukemia or lymphoma cells that express the $\alpha(1,3)$ gal epitope because the cells have been incubated in the presence of recombinant $\alpha(1,3)$ galactosyltransferase in solution and also neuraminidase (see abstract and page 504-505). Galili teaches that for the use of the cells as a vaccine the cells are irradiated (see page 506 and page 508, 2nd column). Galili fails to teach leukemia or lymphoma cells that have been transformed with $\alpha(1,3)$ galactosyltransferase encoding cDNA, or a specific type of cancer cell.

However, Link, Jr (7,005,126) teaches a method of transforming human A375 melanoma cells with murine $\alpha(1,3)$ galactosyltransferase cDNA as well as ovarian and colon carcinoma cells, and teaches that such cells express α -gal (see column 18, line 7- column 19, line 4), and that in athymic nude mice, transformed cells that have been exposed to human serum ex vivo do not form tumors. Yoshimura teaches the transformation of human MIA PaCa-2 human pancreatic cell line, and the huH7, human hepatocellular cell line with bovine $\alpha 1-3$ galactosyltransferase cDNA. The transformed cells produce the $\alpha(1,3)$ gal epitope, and are lysed by human antibodies (see abstract, and page 156, 2nd column). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Galili and those of either Link, Jr. or Yoshimura to make tumor cell vaccines that comprise attenuated tumor cells transformed with nucleic acid encoding $\alpha(1,3)$ galactosyltransferase for the purpose of creating cells that express the $\alpha(1,3)$ gal epitope. One would have been motivated to use Link, Jr.'s or Yoshimura's method because Link, Jr. demonstrates that using the method of transforming human tumor cells creates cells that express the $\alpha(1,3)$ gal epitope, and Yoshimura demonstrates the same method in other types of human cancer cells. One would have had a reasonable expectation of success because Galili teaches that tumor cells expressing this epitope are opsonized by the natural anti-Gal IgG present in human serum, leading to effective phagocytosis by APCs that then transport the vaccine cells to draining lymph nodes for presentation of tumor-associated antigens resulting in activation of tumor-associated antigen-specific helper and cytotoxic T cells (see abstract).

Response to arguments:

Applicants assert that the combination of references fails to teach all of the elements of the claimed compositions, because there is no teaching of cells that are allogeneic to a patient.

While this limitation would carry weight in a claim to a method of treatment, in a claim to a composition, the allogenicity of the cells appears to be limitation directed to the intended use of the cells and not the physical characteristics of the cells encompassed by the claims.

Additionally, all of the arguments presented by applicants against combining the cited references are directed toward the intended use of the claimed cells instead of the cells themselves. Such arguments may be persuasive for method claims, but are not persuasive for composition claims.

The difference between Gallili and the claimed inventions is that Gallili's cells, which express the $\alpha(1,3)$ gal epitope, do not contain a vector comprising $\alpha(1,3)$ galactosyltransferase cDNA (because the $\alpha(1,3)$ gal epitope is created by a different method). However, it was known in the art that transformation with such a cDNA would produce cells that expressed the $\alpha(1,3)$ gal epitope, and because this was a method known to produce the $\alpha(1,3)$ gal epitope in cells and because Gallili, Link, Jr. and Yoshimura taught the desirability of creating the $\alpha(1,3)$ gal epitope one would have been motivated to have combined the references to make the claimed inventions.

10. Claims 1-4 and 85 are rejected under 35 U.S.C. 103(a) as being obvious over Galili (Galili, U. et al., Journal of Hematotherapy & Stem Cell Research 10: 501-511, 2001; cited in IDS) in view of Link, Jr. (Link, Jr. et al., US 7,005,126 B1, issued Feb. 28, 2006; effective filing date June 8, 1999) or Yoshimura (Yoshimura, N. et al., Cancer Letters, 164: 155-160, 2001, March; cited in the IDS), and further in view of ATCC (ATCC Cell Lines and Hybridomas, 8th edition, 1994, page 100).

The combination of Galili with either Link, Jr. or Yoshimura teaches as set forth above with respect to claims 1-3 and 85. The combination of Galili with either Link, Jr. or Yoshimura fails to teach a vaccine tumor cell composition of claim 1 where the cells are from A549 cells. However, A549 cells are known in the art and are commercially available as evidenced by the 1994 ATCC catalog on page 100. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used A549 cells in the methods of either Link, Jr. or Yoshimura to make a pharmaceutical composition for inhibiting tumor growth, where the A549 cells have been transformed with an α -(1,3) galactosyltransferase encoding sequence to make cells that have α -gal epitopes as taught by Galili. One would have been motivated to have used A549 cells because these are human lung cancer cells (see ATCC catalog, page 100) and transforming these cells would make them susceptible to antibody-mediated cell killing which would enhance the presentation of all of the lung tumor cell antigens to the hosts immune system. One would have had a reasonable expectation of success because both Link, Jr. and Yoshimura successfully transform multiple types of cancer cells and produce cells that express α -gal epitopes.

Response to arguments:

Applicants present similar arguments to those presented above. Applicants assert that the combination of references fails to teach all of the elements of the claimed compositions, because there is no teaching of cells that are allogeneic to a patient. While this limitation would carry weight in a claim to a method of treatment, in a claim to a composition, the allogenicity of the cells appears to be limitation directed to the intended use of the cells and not the physical characteristics of the cells encompassed by the claims. Additionally, all of the arguments

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presented by applicants against combining the cited references are directed toward the intended use of the claimed cells instead of the cells themselves. Such arguments may be persuasive for method claims, but are not persuasive for composition claims.

11. Claims 1 and 66 are rejected under 35 U.S.C. 103(a) as being obvious over Galili (Galili, U. et al., Journal of Hematotherapy & Stem Cell Research 10: 501-511, 2001; cited in IDS) in view of Link, Jr. (Link, Jr. et al., US 7,005,126 B1, issued Feb. 28, 2006; effective filing date June 8, 1999) or Yoshimura (Yoshimura, N. et al., Cancer Letters, 164: 155-160, 2001, March; cited in the IDS), and further in view of Berd (US 6,333,028; issued Dec. 25, 2001; effective filing Aug. 14, 1998).

Claim 66 is drawn to a composition of claim 1 and further comprising an adjuvant.

The combination of Galili and either Link, Jr. or Yoshimura teach the composition of claim 1 as set forth above. The combination fails to teach a composition of claim 1 in combination with an adjuvant. However, the use of adjuvants in the vaccines comprising attenuated or killed cells is known in the art as evidenced by the teachings of Berd. Berd teaches the use of adjuvants in a hapten modified tumor cells, where the adjuvants are BCG, QS-21 or IL-12, for example (see column 8, lines 40-51). Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the compositions that are taught by the combination of Galili with either Link, Jr. or Yoshimura, because the use of adjuvants for tumor cell-based vaccines is known in the art, and because adjuvants are known in the art to increase an immune response to components of vaccine compositions.

Response to arguments:

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Applicants present similar arguments to those presented above. Applicants assert that the combination of references fails to teach all of the elements of the claimed compositions, because there is no teaching of cells that are allogeneic to a patient. While this limitation would carry weight in a claim to a method of treatment, in a claim to a composition, the allogenicity of the cells appears to be limitation directed to the intended use of the cells and not the physical characteristics of the cells encompassed by the claims. Additionally, all of the arguments presented by applicants against combining the cited references are directed toward the intended use of the claimed cells instead of the cells themselves. Such arguments may be persuasive for method claims, but are not persuasive for composition claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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12. Claims 1-5, 66, 67 and 85 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/013,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application no. 11/013,685 are drawn to a sub-genus of compositions encompassed by the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' remarks are noted with respect to the possibility of filing a terminal disclaimer should allowable subject matter be identified.

New Grounds of Rejection:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 99 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 99 is indefinite because “the patient” lacks antecedent basis.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
December 26, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER